K070079

Special 510k Submission
X3C Digital Radiographic Imager

JAN 3 1 2007

Summary Statement:

The X3C Digital Radiographic Detector (510k submission device) is substantially equivalent to the Xaminer (predicate device). The CCD imagers in both the X3C Digital Radiographic Detector (510k submission device) and the Xaminer (predicate device) are identical. Traditionally the Xaminer (predicate device) has been fitted into existing radiography systems. The X3C Digital Radiographic Detector (510k submission device) is a modified imager will also be fitted into existing radiography systems.

Information supporting claims of substantial equivalency, as defined under the Federal Food, Drug, and Cosmetic Act respecting safety and effectiveness, is summarized below. For the convenience of the Reviewer, this summary is formatted in accordance with the Agency's final rule: "... 510(k) Summaries and 510(k) Statements..." (21 CFR §807) and can be used as a substantial equivalency summary for anyone requesting it from the Agency.

The X3C Digital Radiographic Detector (510k submission device) is substantially equivalent to the Xaminer (predicate device). The replacement of the scintillator for the submission device is the only significant change between the two imagers. Both submission and predicate devices have the same technological aspects, methods of operation, power sources, controls, user interfaces, and product configuration – with the exception of the scintillator on the X3C Digital Radiographic Detector (510k submission device)

The X3C Digital Radiographic Detector (510k submission device) and the Xaminer (predicate device) are substantially equivalent. Differences, where they exist involve the scintillator; these are not significant and do not raise new questions of safety or effectiveness. The X3C Digital Radiographic Detector (510k submission device) provides users an option to buy a new imager to integrate into their existing radiography systems.

The Xaminer (predicate device) received extensive pre-market product testing, using USFDA recognized performance Standards and recognized ISO, IEC, and harmonized EN standards conducted by an accredited independent test laboratory. Five years of clinical data/field experience involving millions of examinations on human patients demonstrates the Xaminer (predicate device) is safe, effective and performs as intended. The replacement of scintillator to the Xaminer (predicate device) to create the X3C Digital Radiographic Detector (510k submission device) represents no new or added hazards.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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Ms. Shirantha Samarappuli
Manager-Regulatory Affairs
Imaging Dynamics Company, Ltd.
Suite 151, 2340 Pegasus Way NE
CALGARY ALBERTA T2E 8M5
CANADA

AUG 23 2013

Re: K070079
Trade/Device Name: X3C Digital Radiographic Detector
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: January 5, 2007
Received: January 9, 2007

Dear Ms. Samarappuli:

This letter corrects our substantially equivalent letter of January 31, 2007.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Special 510k Submission
X3C Digital Radiographic Imager

Indications for Use

510(k) Number (if known): K070079

Device Name: X3C Digital Radiographic Detector

Indications for Use:

The X3C (510k submission device) is integrated into the user's stationary radiography system. This typical configuration permits a qualified/trained doctor or technologist to take a range of head-to-toe diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts on both adult and pediatric patients. Applications can be performed with patient sitting, standing or lying in the prone or supine positions in an integrated system.

The X3C (510k submission device) is not intended for mammography.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K070079